K111678 ('15)

510(k) Summary of Safety and Effectiveness

FEB - 7 2012

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM: Ortho Solutions Limited
West Station Buisness Park
Spital Road
Maldon
ESSEX, CM9 6FF
United Kingdom

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372
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DATE: April 20, 2011

TRADE NAME: **Ortho Solutions - Extremity Fixation Implants for Osteosynthesis**

COMMON NAME: Bone Fixation Plate, Bone Fixation Screw, Cannulated Bone Screw & Washer, Memory Staple, Bone Screw, Bone Plate, Compression Screw, Internal Fixation Device (non-spinal), Fixation Staple

CLASSIFICATION: Smooth or threaded metallic bone fixation fastener (***per 21CFR888.3040***) – Screw, Fixation, Bone

Single/multiple component metallic bone fixation appliance and accessories (***per 21CFR888.3030***) – Plate, Fixation, Bone; Staple, Fixation, Bone; Washer, Bolt Nut

DEVICE PRODUCT CODE: **HRS**

SUBSEQUENT PRODUCT CODE: **JDR, HWC**

SUBSTANTIALLY EQUIVALENT DEVICES
'Foot Plating System' Ascension Orthopedics (**K022325, K022324**)
'Foot Plating System' Wright Medical Tech. (**K061808, K100359**)
'Memo Staple System' Memometal Technologies (**K070031**)
'Memo Staple System' DePuy Orthopedics (**K060746, K964226**)
'Memo Staple System' Biopro (**K061798**)
'Foot Osteotomy System' Biomet/EBI (**K092670**)
'Foot Osteotomy System' TriMed (**K050681**)
'Staples System' Wright Medical Tech. (**K043059**)
'Staples System' Small Bone Innovations (**K071479**)
'Compression Screws System' Wright Medical Tech. (**K082320**)
'TwistFix™ Snap-Off Screws System' Wright Medical Tech. (**K050819, K042583**)
'Extremity Fixation System' Arthrex (**K103705, K963118**)
'Extremity Fixation System' Ascension Orthopedics (**K060026**)
'Extremity Fixation System' Acumed (**K963118**)

Ortho Solutions Limited - 510(k) Summary:

DEVICE DESCRIPTION:

The *Ortho Solutions Extremity Fixation Implants for Osteosynthesis* consists of Predicate Trauma Implant components commonly found with large companies with orthopedic markets in the United States. These 'small bone extremity trauma implant devices' consist of the following categories:

1. **Foot Plating System (FPS)**
2. **Memo Staple System**
3. **Foot Osteotomy System (FOS)**
4. **Staples System**
5. **Compression Screws System**
6. **TwistFix™ Snap-Off Screws System**
7. **Extremity Fixation System (EFS)**

A brief and concise description of each system is enclosed as follows:

1. Foot Plating System (FPS): The *Ortho Solutions Foot Plating System (FPS)* is designed to address a variety of indications in rearfoot, midfoot, and forefoot reconstuctive fixation surgery. The overall system is composed of a smaller 2.7mm and larger 3.5mm locking/non-locking plating category of system(s). The 2.7mm system of three(3) plate designs consisting of a Universal Locking Plate 2.7 (ULP-2.7), a MetaTarso Phalangeal Plate (MPT), and a Open Wedge Locking Plate (OWL) – all utilized with either a locking or non-locking 2.7mm Screw in various lengths. The 3.5mm system of seven(7) plate designs consisting of a Universal Locking Plate 3.5 (ULP-3.5), a Lapidus Plate(LAP), a Arthrodesis Wedge Plate (AWP), a Rearfoot Reconstuction Plate (RRP), a Tarsal Fusion Plate (TFP), a Calcaneal Step Plate (CSP), and a Calcaneal Locking Plate (CLP) – all utilized with either a locking or non-locking 3.5mm Screw in various lengths. A 3.5mm Cannulated Screw System in various lengths with Washer is also included in the FPS System. Associated instrumentation such as trial plates, disposable drills & wires/guide wires, and ancillary instrumentation is available. All plates, screws, and washer are manufactured from high strength 6-4 Alloyed Titanium to ASTM F136. All plates, screws and washer are offered 'sterile' to the customer.

2. Memo Staple System: The *Ortho Solutions Memo Staple System* consists of four(4) staple sizes (at 10mm, 12mm, 20mm, and 25mm) manufactured from a Nickel-Titanium Nitinol material according to ASTM 2063 for foot reconstruction fixation/arthrodesis procedures. Only the room temperature superelastic properties of the nitinol material with the use of 'spreader/expander instrumention' is utilized in the surgical procedure to enact compression.

Associated instrumentation such as templates, spreaders, expanders, guides, disposable drills and ancillary instrumentation is available. All Memo Staples are offered 'sterile' to the customer.

3. Foot Osteotomy System (FOS): The *Ortho Solutions Foot Osteotomy System(FOS)* consists of a Nail Plate/Staple with Screws in various lengths and Cannulated/Non-cannulated Compression Screws in various lengths for performing metatarsal/phalangeal osteotomies and/or small bone fixation reconstruction. All components are manufactured from CP Titanium to ASTM F67 and high strength 6-4 Alloyed Titanium to ASTM F136. Associated instrumentation such as guide wires, disposable drills and ancillary instrumentation is available. All staple plate/screw and compression screws are offered 'sterile' to the customer.

4. Staples System: The *Ortho Solutions Staples System* is composed of a Varisation Staple (smooth), a Compression Varisation Staple (tapered and ribbed), a Compression Staple (in 11mm, 12mm, 13mm, 15mm, and 20mm and width sizes), and a Blount Staple (in 22mm and width sizes) that are barbed/ribbed, angled, and smooth staple components manufactured from high strength 316LVM surgical grade stainless steel material according to ASTM F138. These staple systems are utilized for fixation of bone fractures or bone reconstruction and for fixation of soft tissues. A 'spreader instrument' is used to deform the compression staple diamond shape for bone compression fixation. Associated instrumentation such as spreaders and expanders with disposable drills and ancillary instrumentation is available. All Staples are offered 'sterile' to the customer.

5. Compression Screws System: The *Ortho Solutions Compression Screws System* consists of Cannulated Meta Compression and Cannulated Compression Screws in various lengths at a diameter of 3.0mm and is used for bone reconstruction in small bone extremities. All compression screws are manufactured from high strength alloyed Titanium to ASTM F136. Associated instumentation such as guide wires and disposable drills and ancillary instrumentation is available. All compression screws are offered 'sterile' to the customer.

6. TwistFix™ Snap-Off Screws System: The *Ortho Solutions TwistFix™ Snap-Off Screws System* comes in a 2.0mm and 2.5mm diameter with various lengths. All TwistFix™ Snap-Off Screws are manufactured from high strength 6-4 Alloyed Titanium to ASTM F136 and CP Titanium to ASTM F67 and are utilized in metatarsal/ phalangeal small bone fixation/osteotomy procedures. Ancillary instrumentaion with disposable drills is available. All TwistFix™ Snap-Off screws are offered 'sterile' to the customer.

Ortho Solutions Limited - 510(k) Summary:
DEVICE DESCRIPTION CONTINUED:

7. Extremity Fixation System (EFS): The *Ortho Solutions Extremity Fixation System (EFS)* consists of various Cannulated and Non-cannulated Flat Head low profile Fixation Screws in diameter sizes of 2.0mm, 2.4mm, 2.7mm, and 3.5mm, in various lengths and are manufactured from high strength 6-4 Alloyed Titanium material to ASTM F136. These flat head screws allow for a low-profile head-on the cortex bone surface for reduction of tissue irritation. Associated instrumentation such as guide wires, disposable drills and ancillary instrumentation is available. All Flat Head Screws are offered 'sterile' to the customer.

INTENDED USE:

The ***intended use*** of the *Ortho Solutions Extremity Fixation Implants for Osteosynthesis System* of bundled fixation device(s) is to draw two or more aligned small bone fragments together to facilitate healing. The *Ortho Solutions Extremity Fixation Implants for Osteosynthesis System* is used in adult patients.

The Ortho Solutions *Foot Plating System (FPS)* is indicated for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the feet, ankles, and toes skeleton.

The Ortho Solutions *Memo Staple System* is indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis. The Memo Staple is also indicated for use in fixation of soft tissue to bone such as anterior cruciate reconstruction.

The Ortho Solutions *Foot Osteotomy System (FOS)* is indicated for alignment and stabilization of small bone fractures including: fixation of small bones, such as those in the foot and ankle for treatment of fractures, non-unions, or mal-unions; ligament reconstructions; osteochondritis dissecans; arthrodesis of the foot and ankle; small bone osteotomies, including first metatarsal head osteotomy and metatarsal osteotomies.

The Ortho Solutions *Staples System* is indicated for fixation of bone fractures or bone reconstruction. The staples are also indicated for use in fixation of soft tissue to bone.

The Ortho Solutions *Compression Screws System* is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.

The Ortho Solutions *TwistFix™ Snap-Off Screws System* is indicated for fixation of bone fractures or for bone reconstruction. Examples include: 1) Fixation of small bone fragments, 2) Weil Osteotomy, 3) Mono-cortical fixation, and 4) Osteotomies and fractures fixation in the foot and hand.

INTENDED USE CONTINUED:

The Ortho Solutions *Extremity Fixation System (EFS)* of a low profile head screw is indicated for use in fixation of small bone fractures, non-unions, arthrodesis, and osteotomies of the small bones in the hand or foot.

The Ortho Solutions Extemity Fixation Implants for Osteo-synthesis System is not intended for spinal use.

EQUIVALENCE:

The *Ortho Solutions Extremity Fixation Implants for Osteosynthesis* is substantially equivalent to predicate systems from many orthopedic companies (as listed).

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS.

The *Ortho Solutions Extremity Fixation Implants for Osteosynthesis* are **identical** in Material, Geometry Design/Markings, and Indications to many predicate system marketed and sold in the U.S.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The *Ortho Solutions Extremity Fixation Implants for Osteosynthesis* is shown to be safe and effective for use as 'sterile' and for single-use in a surgical setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ortho Solutions, Limited
% Engineering Consulting Services, Incorporated
Mr. Al Lippincott
U.S. Agent and Official Correspondent to Ortho Solutions, Limited
3150 East 200th Street
Prior Lake, Minnesota 55372

FEB - 7 2012

Re: K111678
Trade/Device Name: Ortho Solutions Extremity Fixation Implants for Osteosynthesis
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/ multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS, HWC, JDR
Dated: January 18, 2012
Received: January 24, 2012

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ORTHO SOLUTIONS

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www.orthosolutions.com

Indications for Use

510(k) NUMBER: K111678

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Registered Office: West Station Business Park, Spital Road, Maldon, Essex CM9 6FF
Registered in England No: 4311933

K111678(2/2)

ORTHO SOLUTIONS

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Indications for Use Continued:

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Prescription Use __X__ AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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510(k) Number K111678